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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,169	04/27/2005	Andrew David Bacon	Q85454	9237

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
LIETO, LOUIS D	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/520,169	BACON ET AL.	
	Examiner	Art Unit	
	Louis D. Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 17-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the Restriction requirement was received on 02/07/2006. Claims 1-24 are pending in the instant application. Applicant's election with traverse of group III, claims 13-16, drawn to a method of generating an immune response in an animal by administering a composition comprising a nucleic acid and an assistor protein comprising vesicles formed of amphiphilic components, is acknowledged.

Claims 1-12 and 17-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/12/2006.

Response to Arguments

Applicant's election with traverse of group III in the reply filed on 2/07/2006 is acknowledged. The traversal is on the ground(s) that there is a common unifying special technical feature. This is not found persuasive because as previously stated:

Inventions I-IV lack a unifying special technical feature. The applicant provided reference of WO 97/28818 (14.08.97), hereafter referred to as Craig et al., teaches the administration of a nucleic acid encoding a first epitope and a protein containing a second epitope (Abstract). Craig et al. teaches that the first and second epitopes are preferably epitopes from the same antigen, and that the first and second epitope may comprise the same immuno-dominant epitope (pg. 4, lines 25-35). Further, the applicant provided reference of Gregoriadis et al. (1999) Methods 19: 156-162; Abstract, discloses liposomes for the use as vaccines that contain protein antigens as well as antigen encoding DNA vaccines. Therefore, it would have been obvious to the ordinary practitioner in the art at the time of the instant invention to use a liposome to administer a vaccine comprising a nucleic acid encoding an epitope and a protein that contains the same epitope in view of the teachings of Craig et al. and Gregoriadis et al. The cited prior art provides the requisite teaching, suggestion and motivation to make and use the claimed invention.

Since the claimed subject matter was known from the prior art document of Craig et al.,

and Gregoriadis et al. the subject matters of claims 1-24 are not so linked as to form a single general inventive concept (Rule 13.1 PCT) as they appear not to be linked by a new and inventive common special technical feature in the sense of Rule 13.2 PCT by taking into account the state of the art.

Since the unity of invention was broken by the teachings of Craig et al., and Gregoriadis et al. the restriction is appropriate.

The requirement is still deemed proper and is therefore made FINAL.

Claims 13-16 are under consideration.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because of the use of the phrases "said nucleic acid" and "said assistor protein". Correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 13-16 are objected to because of the following informalities: Claim 13 depends from withdrawn claim 1. For the purposes of prosecution the limitations of claim 1 that pertain to the elected invention will be read into the claims. It would be remedial to amend claim 13 so as to provide an adequate of the composition, rather than referring to claim 1.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Europe on 07/05/2002. It is noted, however, that applicant has not filed a certified copy of application No: 02254733.5 as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of generating an immune response in a mammal by administering to the mammal a liposomomal composition comprising a nucleic acid and an antigenic protein within the same vesicle, wherein the nucleic acid encodes said antigenic protein, or at least one epitope of said protein, does not reasonably provide enablement for a method of generating an immune response in any animal, or a method of conferring immunity to any infectious agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims are drawn to a method of generating an immune response in any animal from any species in response to administration of a composition, comprising a nucleic acid and an

assistor protein within the same vesicle formed of amphiphilic components, wherein the nucleic acid encodes an antigenic protein, which shares at least one epitope with the assistor protein, wherein the immune response may be antigen specific antibodies, stimulation of CTLs or immunity against an infectious agent.

The specification does not provide an enabling disclosure for inducing an immune response in any species of animal, other than a mammal, with the claimed method. The kingdom Animalia comprises species with vastly different immune systems, including snails, parrots, worms, fish, sea anemones and mammals. For many species of non-mammalian animals it is unknown in the art if they have an adaptive immune system, or produce cells homologous to cytotoxic T cells or even antibodies. Most of the lower animal species utilize innate pattern recognition receptors as their primary defense against antigens {Pancer et al. (2006) Ann R. Immunology doi:10.1146/annurev.immunol.24.021605.090542; Abstract}. Animal species without innate immune systems will not produce antibodies or a CTL mediated immune response as claimed. Given the teachings in the art and the lack of guidance in the specification on the practice of the claimed invention in any species of animal, other than mammal, the skilled artisan would be able to determine how to practice the invention in a manner commensurate in scope with the claims.

Further, claim 16 is limited to a method of conferring immunity in any animal against infection by any infectious agent after vaccination with said composition. This claim encompasses a method capable of inducing immunity against any parasitic, bacterial, viral or prion infection in any animal, from any species. The term immunity is generally considered to mean the non-susceptibility of an organism to a particular infection or disease. However, the

specification only provides guidance that the claimed method was capable of producing a prophylactic immune response in some mice challenged with a live influenza virus (Specification pg. 45) Even amongst the challenged mice, 7% were infected with the mice over the time frame measured (5 days). The experiments presented do not suggest that the claimed invention can produce immunity against any infectious agent, given that 7% of the tested mice were susceptible to the influenza virus. Further, the specification only describes immunization with plasmid encoded HA and the HA protein. This antigen is well known in the literature to induce a strong immune response in mammals against the influenza virus. However, as applicant's own results attest, even this combination was not capable of inducing immunity in all mice tested. Therefore given the teachings in the specification, a practitioner in the art would not be able to predict how to practice the claimed method so as to confer immunity in any animal against infection by any infectious agent, without extensive and undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is drawn to "immunity against infection by an infectious agent, preferably a virus." A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim

does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 16 recites the broad recitation an "infectious agent", and the claim also recites "preferably a virus" which is the narrower statement of the range/limitation. It would be remedial to amend claim 16 so as to remove the phrase "preferably a virus" and to place this limitation in a dependent claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent NO: 6,166,177 (12.26.2000), hereafter referred to as Probst et al.

Probst et al. provides guidance on a method of generating an immune response in an animal to a vaccine composition (Col. 9, lines 1-15). Wherein the composition comprises a DNA

encoding a Chlamydia polypeptide and may be administered simultaneously with the Chlamydia polypeptide (Col. 8, lines 52-60). Finally, wherein the vaccine composition may be incorporated into a liposome prior to administration (Col. 8, lines 15-27). Therefore, by teaching all the limitations of the claims as written, Probst et al. clearly anticipates the instant invention as claimed.

It is noted that applicant's claims contain the limitation that the immune response comprises an antibody response, involves stimulation of cytotoxic T-lymphocytes or confers immunity. However, the method steps of Probst et al. anticipate the steps of the invention as claimed. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). Thus applicant needs to provide evidence or arguments that the prior art would not lead to an antibody response, involve stimulation of cytotoxic T-lymphocytes or confer immunity.

Claim 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/28818 (14.08.97), hereafter referred to as Craig et al.

Craig et al., provides guidance on the administration of a nucleic acid encoding a first epitope and a protein containing a second epitope to a mammal (Abstract). Craig et al. teaches that the first and second epitopes are preferably epitopes from the same antigen, and that the first and second epitope may comprise the same immuno-dominant epitope from an infectious agent, such as the influenza virus (pg. 4, lines 25-35; claims 24-30). Wherein said method is designed to provide long-lasting immunity (pg. 2, lines 15-20). Further, wherein said method induces a cytotoxic T cell response and an antibody response (pg. 6, lines 1-10). Finally, Craig et al. teaches that the a nucleic acid encoding a first epitope and a protein containing a second epitope may be administered using a delivery vehicle, such as a liposome, (pg. 12, lines 10-25). Therefore, by teaching all the limitations of the claims as written, Craig et al. clearly anticipates the instant invention as claimed.

No Claims allowed.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with,

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Dr. Louis D. Lieto
Patent Examiner
Art Unit 1632

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1630